Section 1: Scheduled Maintenance of the service manual defines the required preventive maintenance for keeping the Medfusion™ 3000 Series syringe infusion pump in good operating condition.

Preventive Maintenance Planning

The recommended preventive maintenance plan allows you to service pumps in batches as their anniversary dates arrive. For example, if you have numerous pumps to service over the course of a year you may want to set the date on each pump so that 10 pumps are due for service each week of the year (this will prevent all pumps from giving the alert reminder at the same time).

Pumps with **V3 software**: enter the ***last*** PM date (the pump will calculate the next PM date). An example of a plan for the maintenance of pumps with V3 software is shown in the following table:

Serial Numbers	Scheduled PM	Enter Last PM	Date of Alarm
M001001 to M001010	7/24/2007	**7/24/2005**	7/25/2007
M001011 to M001020	7/31/2007	**7/31/2005**	8/1/2007

Pumps with **V4 software**: enter the ***next*** PM date. An example of a plan for the maintenance of pumps with V4 software is shown in the following table:

Serial Numbers	Enter Next PM Date	Last PM	Date of Alarm
M001001 to M001010	**7/24/2008**	7/25/2007	7/25/2008
M001011 to M001020	**7/31/2008**	8/1/2007	8/1/2008

The best approach is to set the date so that the alarm occurs only if a pump is missed in the normal PM schedule.

Biomed maintenance tools

In order to complete maintenance, parts replacement, diagnosis and calibration of Medfusion™ 3000 Series infusion pumps, you will need the following:

1 ea – Calibration Kit (see service parts list): Small Calibration Slug, Large Calibration Slug & Force Gauge

1 ea – new 50 or 60 cc syringe (note: the lubrication in syringes evaporates, change "test" syringes monthly)

1 ea – 3-way Stopcock

1 ea – Electrical Safety Analyzer

1 ea – Torque Screwdriver w/Phillips & Standard bits.

1 ea – ¼" open end wrench

1 ea – 6" calipers with resolution of 0.001"

Using a torque screwdriver

You **must** always use a *Torque Screwdriver* when reassembling any Medfusion™ 3000 Series pump. Where screws are used to secure components, over-tightening can strip threads or crack standoffs in the case.

- Unless otherwise specified, you should always torque all screws to 60 *in-oz* (approximately 0.8 Nm).

Electrostatic-controlled workstation

Whenever you work on the Medfusion™ 3000 Series pump – *specifically whenever you open the pump for service* – you **must** work in an electrostatic-controlled environment. This ensures you will not damage the electronic components in the pump.

WARNING: Repair Pump in ESD Controlled Work Area: The pump case should only be opened at a work-station with Electrostatic controls, including a grounded mat and wrist-strap.

Service warnings

WARNINGS:

• ***Pump Maintenance:*** **Only trained biomedical service personnel may service this pump**. Service personnel should disconnect the AC power cord before servicing the pump.

• ***AC Power:*** **The only means of removing AC power is to disconnect the AC power cord.** While the AC power cord is attached to the pump and plugged into an AC outlet, live mains voltage is present within the pump.

• ***Manufacturer Recommended Maintenance:*** **Always maintain this pump following *manufacturer recommended instructions*** in this Service Manual. An improperly maintained pump may cause serious injury to a patient or user.

Periodic maintenance

This maintenance is ***required*** for the continued safe operation of Medfusion™ 3000 Series pumps.

The Medfusion™ 3000 Series pump must be tested annually, or whenever the pump has been damaged or dropped. Always check all sensor calibrations as a standard part of annual maintenance. No calibration is required to maintain pump flow delivery accuracy.

Installation/quick check-out

Each pump is inspected and tested prior to shipment from the factory. Some institutions require that devices entering a hospital be functionally checked before being placed into service. The following procedure is provided to meet this need.

Quick check-out test

- ☐ 1) Plug AC power cord into AC receptacle on side of pump, then plug pump into an AC power (100 to 240 VAC) source. Verify AC indicator and battery charge indicator are lit.
- ☐ 2) Press **Power**. Verify the following on power-up:
  - Verify alarm beeps.
  - Verify all the LED indicators are turned on & off (except AC and battery).
  - Verify that no self-tests fail.
  - Verify the display is legible and contrast is acceptable.
- ☐ 3) Unplug the AC power cord and verify that within several seconds the battery indicator begins to flash and AC indicator goes off. Re-plug the AC power cord into the unit.
- ☐ 4) Perform the "Flow Delivery Accuracy Test" from *Annual Maintenance* (which follows).
- ☐ 5) From the pump's **Main** screen, use the number buttons to choose **Biomed** (press **More** for second page, if needed). Use the number buttons to enter passcode "***2580***", then use the number buttons to choose **Utilities**. Then:

  Set/view Last PM Date. ***Pumps with V3 software:*** Set the PM date to today's date. (Setting this PM date means that an advisory message will appear on the pump two years from this date.) - ***OR*** -

  Set/view Next PM Date. ***Pumps with V4 software:*** Set the date to the date you ***want*** the PM alert to occur. Select #3, Select #1

  This message does not prevent normal operation of the pump, but advises the user that maintenance is recommended.) [Note: pumps are shipped from the factory with the date/time set to USA Central Standard Time; use the **Set Time/Date** utility to modify this if desired.]
- ☐ 6) Perform the "AC Line Leakage Test" from *Annual Maintenance* (which follows).
- ☐ 7) Consult the troubleshooting guide or contact Smiths Medical should the pump fail any steps in this test.
- ☐ 8) After the completion of these tests the pump be should plugged into AC power to recharge the battery. [This is recommended when the battery capacity is less than 90% – look at battery gauge displayed on the bottom of the power-up screen.]

Cleaning and care

Standard cleaning of Medfusion™ 3000 series pumps

Follow your institution's guidelines for cleaning and disinfecting of devices. The syringe pump can be safely cleaned with the following agents:

- ***Common chlorine bleach diluted with water.***
- ***Mild detergent mixed with water.***
- ***Isopropyl alcohol 70% solution.***
- ***Other surface disinfectants which are compatible with plastic materials.***

For best results: Clean by spraying or pouring cleanser directly ***onto a soft cloth*** (not directly onto the pump) and then wiping surfaces until dry.

Cleaning cautions

Below are standard cautions you should follow when cleaning Medfusion™ 3000 Series pump:

CAUTIONS:

- ***Avoid Organic Solvents:*** Never use organic solvents (e.g., acetone), quarternary ammonia compounds, strong acids or strong bases to clean any portion of the pump.
- ***Not Waterproof:*** The Medfusion™ 3000 Series is "spray resistant" but not "water proof".
Never spray cleaning or other fluids directly into openings on the bottom of the pump.
Never immerse the pump in water or other fluids.
- ***Avoid Spray Oils:*** Never use light spray oils (e.g., WD40™) to clean or lubricate pump. These chemicals can damage the plastic of the pump.
- ***Never Autoclave or Gas Sterilize:*** Never sterilize the pump in a steam autoclave or gas. Using an autoclave or gas sterilization can seriously damage the Medfusion™ 3000 Series pump and void the warranty.

Mandatory annual maintenance testing

All tests on this *Required Annual Maintenance List* must be performed annually in order to ensure the continued safe operation of the Medfusion™ 3000 Series pump.

General inspection

- ☐ 1) If not already performed, clean and disinfect the pump as described in the "*Cleaning and Care*" section (see previous page).
- ☐ 2) Inspect for obvious physical damage, including cracked housings or torn keypads. Repair any physical damage.
- ☐ 3) Verify smooth operation of syringe plunger driver, syringe release lever, syringe flange clip, and syringe barrel clamp. Clean and/or repair any damaged components.
- ☐ 4) Verify the three tubing guides (hooks) on top left side are intact, and fully secured to pump housing. Replace any damaged guides.
- ☐ 5) Verify force sensor seal, located behind flippers on plunger driver head, is intact and not punctured. Replace damaged seal.
- ☐ 6) Inspect power cord for damage and wear. Replace damaged or worn power cord before performing any leakage current testing.
- ☐ 7) Inspect pole clamp for proper operation. Verify that the screws holding pole clamp components are tight.
- ☐ 8) Verify the Serial Number label is legible and intact. Replace if label is damaged.
- ☐ 9) Verify the Warning label is legible and intact. Replace if label is damaged.
- ☐ 10) Verify four rubber feet are attached to the bottom housing of the pump. Replace missing feet.
- ☐ 11) Turn the pump on all sides and check for any loose parts internally and externally.
- ☐ 12) Plug AC power cord into AC receptacle on side of pump, then plug pump into an AC power (100 to 240 VAC) source. Verify AC indicator and battery charge indicator are lit. Consult troubleshooting for any failed indicator.

Power-up test

Ensure that no syringe is loaded in the pump and the barrel clamp is fully down. Press POWER. Verify the following on power-up:

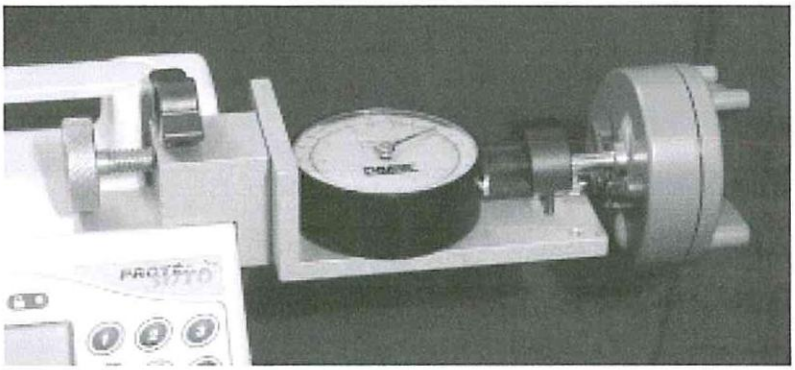
- ☐ 1) Verify alarm beeps.
- ☐ 2) Verify all the LED indicators are turn on and off (except AC and battery).
- ☐ 3) Verify that battery capacity shown on screen is greater than 0%.
- ☐ 4) Verify that no self-tests fail.
- ☐ 5) Verify the display is legible and contrast is acceptable.
- ☐ 6) Unplug the AC power cord and verify that within several seconds the battery indicator begins to flash and AC indicator goes off. Re-plug the power cord into the unit.

Consult troubleshooting for any failed steps in this test.

Calibration verification

From the pump's **MAIN** menu, use the **number** buttons to choose **BIOMED** (press **More** to find it, if needed).
Enter the passcode (numbers ***2580***), then press **Enter**.
Use the number buttons to choose **DIAGNOSTICS**, then **MONITOR ANALOG SENSORS**. → #5

Force sensor check



- ☐ 1) Ensure that no syringe is loaded in the pump. Verify that the force reading on the screen is between –0.2 and +0.2 pounds.
- ☐ 2) Load the force gauge with the foot of the gauge positioned towards the head of the plunger driver. Zero the force gauge. Using the thumbscrew of the force gauge bracket, increase the force applied until the force gauge reads 15 pounds (6.8 kilograms). Verify that the force reading on the screen is between 14.0 and 16.0 pounds.

If either reading is out of specification, re-calibrate the sensor and then retest readings.

Syringe size sensor check

* SYRINGE SIZE SENSOR CHECK & PLUNGER POSITION SENSOR CHECK CAN BE DONE AT THE SAME TIME

- ☐ 1) Load the small Calibration Slug into the barrel clamp (do not load the plunger driver). Keeping the barrel clamp perpendicular to the slug, move the barrel clamp head slightly back and forth to find the lowest size reading.
  Verify that the size reads between 0.256" and 0.272", inclusive.
- ☐ 2) Load the large Calibration Slug into the barrel clamp (do not load the plunger driver). Keeping the barrel clamp perpendicular to the slug, move the barrel clamp head slightly back and forth to find the lowest size reading.
  Verify that the size reads between 1.244" and 1.260", inclusive.

If either reading is out of specification, re-calibrate the sensor and then retest readings.

Plunger position sensor check

☐ 1) Load the small Calibration Slug into the barrel clamp.
Load the plunger driver onto the end of the slug with flippers open, and about 0.1 lbs. applied to force sensor (as read from the screen).
Verify that the position reads between 0.680" and 0.720", inclusive. Unload the slug.

☐ 2) Load the large Calibration Slug into the barrel clamp.
Load the plunger driver onto the end of the slug with flippers open, and about 0.5 lbs. applied to force sensor (as read from the screen).
Verify that the position reads between 4.680" and 4.720", inclusive. Unload the slug.

If either reading is out of specification, re-calibrate the sensor and then retest readings.

***Note**: Use a new syringe for the following tests as the lubrication within syringes evaporates. Change "test" syringes at least monthly.*

Plunger travel test

Return the pump to the **MAIN** menu (press BACK to exit Biomed mode). Load an air-filled 50 or 60 cc syringe into the pump. Use the number buttons to choose **ML/HR** delivery mode and set the flow rate to 20 ml/hr. Clear the total infused. Press START.

☐ 1) Verify the three green infusing indicators are lit in a repeating sequence from right to left. Continue running until at least 0.033 ml has been infused.

☐ 2) Press **Lock** and verify the Lock indicator lights. Press **Unlock** and verify the Lock indicator turns off.

☐ 3) Press **CHG Rate** and set a rate to the maximum rate available on the ml/hr control screen. Allow the unit to drive for the full length of the syringe.

☐ 4) When the syringe is empty, verify the **SYRINGE EMPTY** alarm message is displayed and the red alarm indicator lights. Verify the alarm tone quality. Press 🔔 to silence alarm.

If other alarms or system failures occur during this test use the troubleshooting guide for corrective actions.

Motor drive & occlusion operational test

Connect a three-way stopcock to an empty 50cc or 60cc Luer-lock syringe. Load the syringe with the syringe filled with approximately 30cc of air.

☐ 1) Use the number buttons to choose **ML/HR** mode and set the flow rate to the maximum rate as displayed on the ml/hr entry screen.
From the **BEGIN DELIVERY** screen, press BOLUS to access the **PRIME** screen. Press and hold BOLUS to prime the tubing set for at least 0.2 ml priming volume. Press **Exit**.
Close the stopcock to the syringe.

☐ 2) Press **Options**, use the number buttons to choose **OVERRIDE OCCL LIMIT**, choose **HIGH**, then press **Enter**.

☐ 3) Press **Options**, then use the number buttons to choose **DISABLE RAPID OCCL DETECT**, if available. (If not available, press BACK.)

☐ 4) Press START to begin the infusion.

☐ 5) Verify the pump operates until an occlusion alarm occurs.
Open the stopcock to release the pressure, then remove the syringe.

If any alarm other than occlusion occurs during this test, see troubleshooting for corrective action.

Flow delivery accuracy test

Return the pump to the MAIN menu. Use the number buttons to choose ML/HR. Select a syringe manufacturer. Load a 50/60 cc Luer-lock syringe (air-filled) into the pump – use a syringe from the table below. Enter a rate of 300 ml/hr.

☐ 1) From the BEGIN INFUSION screen, press **Options** and use number buttons to choose VOLUME LIMIT. Enter a volume limit of 50 ml. (Note: if volume limit is not configured, press STOP when TVD reaches 50.0 ml.)
From the BEGIN INFUSION screen, press BOLUS to access the PRIME screen. Press and hold BOLUS to prime the tubing set for at least 0.2 ml priming volume. Press **Exit**.
Use calipers to measure the distance from the outside of the syringe flange to the inside of the syringe plunger. **Record this measurement as the starting position.** _____

☐ 2) Press START and ensure delivery begins. Wait until the pump volume limit is reached in 10 minutes. (Press STOP if volume limit is not active.)
Press 🔔 to silence the audible alarm. Use a set of calipers to measure the distance from the outside of the syringe flange to the inside of the syringe plunger. **Record this measurement as the ending position.** _____

☐ 3) Subtract the ending position from the starting position. Verify that this result is between 3.473" and 3.615" (inclusive) for a B-D 60cc syringe, consult table below for other syringes.

Manufacturer	Minimum travel	Nominal travel	Maximum travel
B Braun Perfusor 50cc	**3.146" (79.92mm)**	3.211" (81.55mm)	**3.275" (83.18mm)**
B Braun Ominifix 50cc	**3.146" (79.92mm)**	3.211" (81.55mm)	**3.275" (83.18mm)**
B-D 60cc	**3.473" (88.22mm)**	3.544" (90.02mm)	**3.615" (91.82mm)**
Fresenius 50cc	**2.904" (73.76mm)**	2.964" (75.27mm)	**3.023" (76.77mm)**
Monoject 60cc	**3.473" (88.22mm)**	3.544" (90.02mm)	**3.615" (91.82mm)**
Terumo 60cc	**2.901" (73.70mm)**	2.961" (75.20mm)	**3.020" (76.70mm)**

Table of acceptable syringe travel for 50 and 60 cc syringes.

If this test fails use the troubleshooting guide for corrective action.

AC line leakage test

☐ 1) Connect the AC power cord to the Safety Analyzer. Set Safety Analyzer to Line Leakage mode of operation. Press POWER to turn the pump on.

☐ 2) Using the ground reference probe of the Analyzer, make contact with either the plunger driver tube or the center post of the DC input jack. Verify the leakage in the normal setting is less than 100 micro-amps [note, this is equivalent to BF rating for this device].

If you wish to verify the CF rating of the pump, then fill a beaker with normal (0.9%) saline solution and load the pump with a syringe and tubing filled with normal saline. The saline-filled tubing should be in contact with the saline in the beaker. Place the ground reference of the leakage current Analyzer in contact with the saline in the beaker and verify the leakage current in the normal setting is less than 10 micro-amps. [This procedure is specified in IEC 60601-2-24, clause 19.]

Turn off pump and disconnect from safety analyzer.

WARNING: ***Safety Class II, Type CF Medical Equipment:*** The pump is listed as Safety Class II, Type CF equipment. Protection against electrical shock does not rely only upon basic insulation, but instead relies on double or reinforced insulation. As such, this equipment does not utilize a third wire ground (earth ground).

Therefore, when doing line leakage test it is not necessary to measure leakage in both the open ground and closed ground setting. Nor is it necessary to perform a ground resistance test.

AC line leakage test - *Medfusion™ 3500BC*

☐ 1) Connect the AC power cord to the Safety Analyzer. Set Safety Analyzer to Line Leakage mode of operation. Press POWER to turn the pump on.

☐ 2) Enclosure Leakage - Using the ground reference probe of the Analyzer, make contact with the center post of the DC input jack. Verify the leakage in the normal setting is less than 100 micro-amps [note, this is equivalent to BF rating for this device].

☐ 3) Earth Leakage - Use the Safety Analyzer, to measure the leakage current flowing through the earth conductor of the AC power cord.

Verify the leakage in the normal setting is less than 100 micro-amps [note, this is equivalent to BF rating for this device].

If you wish to verify the CF rating of the pump, then fill a beaker with normal (0.9%) saline solution and load the pump with a syringe and tubing filled with normal saline. The saline-filled tubing should be in contact with the saline in the beaker. Place the ground reference of the leakage current Analyzer in contact with the saline in the beaker and verify the leakage current in both the normal and reversed settings is less than 10 micro-amps. [This procedure is specified in IEC 60601-2-24, clause 19.]

Turn off pump and disconnect from Safety Analyzer.

WARNING: ***Safety Class II with functional earth, Type CF Medical Equipment:*** The pump is listed as Safety Class II with functional earth, Type CF equipment. Protection against electrical shock does not rely only upon basic insulation, but instead relies on double or reinforced insulation. As such, this equipment utilizes a third wire ground (earth ground) lead of the power cord as earth return for electromagnetic energy and does not serve as a safety function.

Therefore it is neither possible nor necessary to perform a ground resistance test.

Battery maintenance

This chapter discusses battery maintenance as recommended to ensure good battery performance.

1. The battery pack contains six 2100 mAH Nickel Hydride (NiMH) cells (older pumps may have Nickel Cadmium [NiCad] batteries) with a smart gauge for monitoring battery charge information.

Notes:

- *The gauge is built into the battery pack, and the pump reads the battery capacity from the gauge on the pack.*
- *The battery pack has a shelf life of 4 months, after which it will require recharging. Once installed into a pump, the shelf life is 2 months, after which it will require recharging.*

2. There are two measured battery parameters that must be reviewed to maintain good battery performance and accuracy of the battery gauge. From the **Main** menu, use the **number** buttons to choose **Biomed**; use the **number** button to choose **Diagnostics**; use the number buttons to choose **Monitor Battery Status** option.

   a) **LMD (Last Measured Discharge)** – This the *learned capacity* of the battery by the gauge following a calibration cycle. It is recommended the battery be replaced when this value is < *1600 mA-hours.*

   b) **CPI (Capacity Inaccurate)** – This is the *number of shallow discharge cycles* since the last calibration. It is recommended that you recalibrate the battery when CPI is > *80 hex (i.e. >128 decimal).* Refer to the battery calibration section below.

Shallow discharge (CPI) record

The battery gauge records the number of shallow discharges. A *shallow discharge* happens whenever the battery is *partially* discharged and then returned to AC power. The number of the shallow discharges appears on page two of the **Monitor Battery Status** menu in the **Biomed** > **Diagnostics** menu.

- This displays CPI as 0×DD, where 0×DD is a hexadecimal number representing the number of shallow discharges cycles.
- The value is reset to zero each time the battery is calibrated. It increments to a maximum count of 0×FF hex (255 decimal).

During the annual periodic maintenance if the number of shallow discharges, CPI, is 0×80 hex or higher [e.g. 0×90, 0×A5, 0×BB, etc.], then the battery should be re-calibrated.

Battery calibration procedure

The *battery calibration* procedure ensures the battery calibrates (or "re-learns") the battery capacity. It does this by measuring the actual charge & discharge rates to determine the true capacity of the battery. With this correct information, the pump calculates "percentage of battery charge" and determines "low battery alarm".

1. Connect the pump to AC power.
2. Turn the pump on and select **Biomed** > **Diagnostics** > **Monitor Battery Status.**
3. After the Charge Level gauge reaches 99 to 100%, wait at least 1 more hour, then remove AC power.
4. Using one of the methods listed here, fully drain the battery pack, until the pump sounds the **Battery Depleted** alarm (not the **Low Battery** alarm). You can interrupt the discharge test by turning the pump off and continue discharge at a later time – as long as you do not plug the pump into AC power during the discharge cycle.

   a) The battery can be discharged by operating the pump on battery power and infusing at 5 ml/hr using a 60cc syringe. This takes approximately *10 hours* from a full charge.

   b) A quicker method is holding open the clutch lever with an a clamp or vise grips to prevent the plunger flipper and clutch from closing. Then use **Biomed** > **Diagnostics** > **Motor Drive Test**, and set motor step period to 2 msec, and press START. This should deplete the battery within approximately *3 hours* .

   c) A third method is to disconnect AC power, turn the pump on, and run **Biomed** > **Diagnostics** > **Monitor Battery Status**. This discharges the battery at about 130 ma, and takes approximately *13 hours* from full charge.

5. Once the **Battery Depleted** alarm sounds, turn the pump off and plug into AC. This begins recharging the battery. [**Do not unplug AC power until charging is complete.**]

   If left in "Depleted" alarm condition, the pump will draw power from the battery until its voltage drops

to a level which disconnects the battery gauge. ***The pump then loses all its calibration information.*** *From the time the* **Battery Depleted** *alarm occurs, the pump has approximately 5 minutes of operation on battery before the "fully-depleted disconnect" condition occurs. At this point, the audible alarm continues running from the super-capacitor on the main board.*

6. After several minutes of recharging the gauge will show the learned capacity of the battery.
7. Turn the pump on and select **Biomed > Diagnostics > Monitor Battery Status.**
8. Verify LMD (last measured discharge) value is greater than 1600 ma-hours.
9. Press **More** and verify CPI is 0×00 or 0×01.
10. Turn the pump off and continue to charge pump until battery charge is complete (approximately 10 hours).
11. Turn on pump and select **Biomed > Diagnostics > Monitor Battery Status.**
12. Verify the LMD is greater than *1600 mA-hours.* At 1600 mA-hours battery, the pump's battery life is approximately 7-8 hours. It is recommended that the battery be replaced if its capacity is less than 1600 mA-hours.

Requirements for battery pack replacement

The battery must be replaced only by a trained Biomedical or service technician. Always dispose of depleted or defective batteries in compliance with all applicable regulations or you may return the battery pack to Smiths Medical for recycling.

WARNING: ***Battery Replacement:*** Observe ESD handling precautions when replacing the battery.

Replace battery only with same Smiths Medical part/model number.

Recycle batteries in compliance with applicable local regulations.

Collect Separately

This product contains electrical and electronic components (including batteries) that may contain materials, which if disposed of with general waste, could be damaging to the environment.

In accordance with Directive 2002/96/EC Waste Electrical and Electronic Equipment, residents of the European Union must follow specific disposal or recycling instructions for this product. Contact your local distributor, or visit the following web site for specific instructions:

http://www.smiths-medical.com/recycle/index.html

Non-European Union residents must dispose of or recycle this product (including batteries) in accordance with the local laws or regulations that apply.

WARNING: ***Collect Separately.*** There are potential health hazards associated with improper disposal of batteries, electronics, and contaminated (used) infusion sets and syringes. Dispose of used batteries, infusion sets, syringes, and other used accessories, or a pump that has reached the end of its useful life, in an environmentally safe manner, and according to any regulations that may apply.